PATENT
Customer No. 22,852
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
WOLFMAN et al.	Group Art Unit: 1652
Application No.: 10/662,438	Examiner: Chowdhury, Iqbal Hossain
Filed: September 16, 2003	Confirmation No.: 2654
For: METALLOPROTEASE ACTIVATION OF MYOSTATIN, AND METHODS OF MODULATING MYOSTATIN ACTIVITY	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated March 9, 2006, the Examiner required restriction under 35 U.S.C. § 121 between:

Group I- Claims 1-15, drawn to an agent or a peptide that modulates metalloprotease activity, which mediates activation of latent myostatin, by cleavage, classified in class 530, subclass 300.

Group II- Claims 16-19, a method of treating a muscle disorder, classified in class 514, subclass 2.

Group III- Claim 17 and 20, drawn to a method of treating diabetes, classified in class 514, subclass 2.

Group IV- Claim 17 and 21, drawn to a method of treating obesity, classified in class 514, subclass 2.

The Examiner further indicates that each of the inventions of Groups I-IV is further restricted to one of the following peptides:

(A) the peptide of SEQ ID NO:11 (KDVIRQLLPKAPPLRELIDQYDVQRADSSDGSLEDDDYHATTETIITMPT);

(B) the peptide of SEQ ID NO:14 (QLLPKAPPLRELIDQYDVQRADSSDGSLEDDDYHATTETI);

(C) the peptide of SEQ ID NO:17 (QLLPKAPPLRELIDQYDVQRADSSDGSLEDDDYHATTETI);

(D) the peptide of SEQ ID NO:20 (ELIDQYDVQRADSSDGSLED); and

(E) the peptide of SEQ ID NO:23 (YDVQRADSSD).

The Examiner alleges that Groups I and II-IV are related as product and process of use, stating that the inventions are distinct because the peptides of Group I can be used in a materially different process. The Examiner then notes that if the product claims of Group I are elected and are subsequently found allowable, withdrawn process claims of Groups II-IV may be available for rejoinder under MPEP § 821.04. The Examiner further alleges that the peptides of Groups (A)-(E) are unrelated inventions, stating that they represent structurally different polypeptides and polynucleotides encoding them. The Examiner posits that the peptides will have different effects in, for example, hybridization, expression, or antibody binding studies.

In response, Applicants provisionally elect to prosecute Group I, claims 1-15, drawn to an agent or a peptide that modulates metalloprotease activity. Applicants also provisionally elect the peptide of Group E with traverse.

Applicants note that the peptides of Groups (A)-(E) are structurally related; the amino acid sequences of Groups (A)-(E) (SEQ ID NOs:11, 14, 17, 20, and 23, respectively) are peptide portions of the myostatin propeptide of decreasing size. All contain the sequence YDVQRADSSD. Each peptide also comprises an aspartate to alanine substitution within the myostatin propeptide sequence that affects cleavage by a metalloprotease. Therefore, the Examiner has not demonstrated that the peptides have different modes of operation, different functions, or different effects.

In order to require restriction of claims, the Examiner must demonstrate that the subject matter of the claims is independent or distinct and that there would be a serious burden on the Examiner if restriction is not required with respect to the peptide sequences. Manual of Patent Examining Procedure, § 803. Inventions are considered independent if "there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect." Manual of Patent Examining Procedure, § 802.1. The Examiner has not met this burden for the nested set of peptides of Groups (A)-(E).

The Examiner has also failed to explain why there would be a serious burden on the Examiner if the claims were not restricted. MPEP § 808.2. Specifically, the Examiner must show one of the following: (1) classification in separate fields of search; (2) evidence of a separate status in the art when they are classified together, such as patents that demonstrate such separate status; or (3) a different field of search is necessary, even when the subject matter of the claims is classified together. *Id.* The MPEP makes clear that "[w]here, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and

field of search, no reasons exist for dividing among independent or related inventions." *Id.*

For example, Groups (A)-(E) are members of the Markush group of claim 4. These peptides are sufficiently few in number and so closely related that a search and examination of the entire claim can be made without serious burden. *See* MPEP § 803.02. Applicants also respectfully note that while only five amino acid sequences are provided in claim 4, the sequence search rules of MPEP § 803.04 expressly state: "It has been determined that normally ten sequences constitute a reasonable number for examination purposes." MPEP § 803.04 ("The Director has decided *sua sponte* to partially waive the requirements of 37 C.F.R. 1.141 et seq. and permit a reasonable number of [] nucleotide sequences to be claimed in a single application.")

Accordingly, Applicants submit that this requirement for election between Groups (A)-(E) is improper and ask for withdrawal of the restriction requirement and examination of SEQ ID NOS:11, 14, 17, 20, and 23 in this application.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 18, 2006

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